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NEST360°

# Target Product Profile

## Oxygen Concentrator – Respiratory Support

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**Acknowledgements**
This report was prepared by Rebecca Kirby and Kara Palamountain from Northwestern University with input from UNICEF and other stakeholders. The document summarizes consensus achieved at a meeting on target product profiles for newborn care in low-resource settings, convened by NEST360°. This document was finalized following consideration of all comments and suggestions made by meeting participants at the Consensus Meeting.

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**Note to the reader**
Because of the richness of the discussion, and in an attempt to keep this report simple and readable, this report aims to convey the themes addressed in each session, rather than attempting to provide a chronological summary of the dialogue.

*Disclaimer: The TPPs do not replace or supersede any existing UNICEF TPPs. The TPPs do not constitute tender specifications, nor is UNICEF bound to tender or procure products that arise as a result of these TPPs. UNICEF may require regulatory approval and proof of compliance to quality management and product-specific international standards for tendering purposes.*

# INTRODUCTION

At birth, a baby's lungs must transition from fetal to neonatal life in three key ways:

1. fluid in the lungs must be absorbed and replaced with air,
2. lungs must expand fully and regular breathing must be established, and
3. pulmonary blood flow is increased.

When these three things do not happen, a baby will have respiratory distress. Respiratory distress syndrome (RDS) is when there is deficiency of surfactant that is needed to prevent alveolar collapse; this is especially common in premature newborns.

Oxygen provision is important in the care of newborn infants because many conditions that affect babies in the first days of life can result in low levels of oxygen in the body. Hypoxemia, or low levels of oxygen in the blood, is a life-threatening condition that results in increased mortality and morbidity. Prematurity and respiratory distress syndrome (surfactant deficiency), pneumonia and other severe infections, asphyxia, and difficulties in the transition from fetal to neonatal life can all result in hypoxemia. Yet, despite its importance in acute severe illnesses, hypoxemia is often not well recognized or managed in settings where resources are limited. It is therefore important for health workers to know the clinical signs that suggest the presence of hypoxemia and how supplemental oxygen can appropriately be used as an essential lifesaving treatment [1].

For newborns with breathing difficulties and/or infections, oxygen is vital to survival. Yet, access to oxygen can be scarce in low-resource settings. To meet this need, an oxygen concentrator is a device able to concentrate oxygen from the air for use with a multitude of devices. While use of concentrators is helpful, facilities should always have a power-independent oxygen source, such as a cylinder, available for back up.

Oxygen concentrators typically output oxygen between 85-100% FiO2, with flows between 2-10 LPM with typically one or two outlets. The percent oxygen a patient will receive depends on each mode of delivery (i.e., nasal prongs, nasal catheter, facemask, etc.). Passive humidification is sometimes available but recommended against by the World Health Organization [1]. A flow splitter allows the output of a concentrator to be split between multiple patients while independently monitoring and adjusting the flow rate to each. It is important to consider that high flow oxygen concentrators should be paired with an appropriate flow splitter for the safety of the neonate.

# DEVELOPING A TARGET PRODUCT PROFILE

## Overview

Manufacturers need Target Product Profiles (TPPs) at an early stage in the medical device and diagnostic development process. These TPPs help inform the ideal targets and specifications and align with the needs of end users. TPPs outline the most important performance and operational characteristics as well as pricing. In the TPPs to follow, the term "Minimal" is used to refer to the lowest acceptable output for a characteristic and "Optimal" is used to refer to the ideal target for a characteristic. The Optimal and Minimal characteristics define a range. Products should meet at least all of the Minimal characteristics and preferably as many of the Optimal characteristics as possible. TPPs should also specify the goal to be met (e.g. to initiate treatment), the target population, the level of implementation in the healthcare system and the intended end users.

For the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles, an initial set of TPPs were developed listing a proposed set of performance and operational characteristics for 16 product categories. The development timeline envisioned in the TPPs was four years, although some commercially available technologies may fit some of the criteria already. For several of the characteristics, only limited evidence was available and further expert advice was sought from additional stakeholders.

## Delphi-Like Process

To obtain this expert advice and to further develop the TPPs, a Delphi-like process was used to facilitate consensus building among stakeholders. The initial TPPs were sent to a more comprehensive set of stakeholders including clinicians, implementers, representatives from Ministry of Health, advocacy organizations, international agencies, academic and technical researchers and members of industry. In total, 103 stakeholders from 22 countries participated in the TPP development process via survey.

30 respondents participated in the Delphi-like survey for the Oxygen Concentrator.

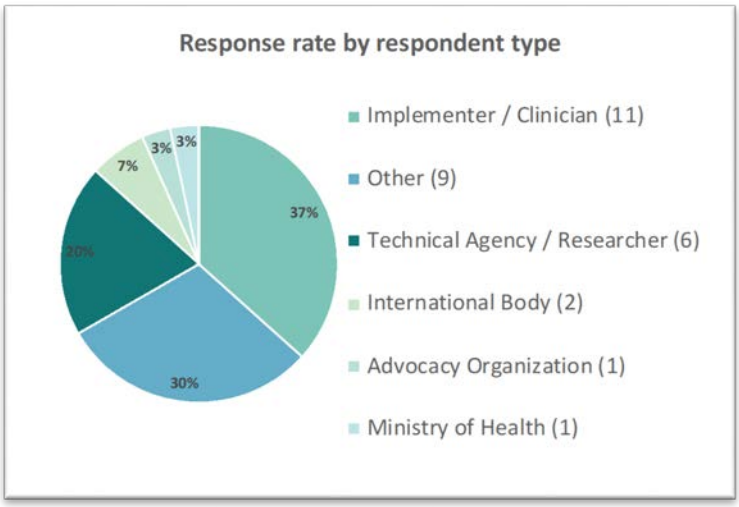
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an option to opt out with the selection of "Other - Do not have the expertise to comment". If participants did not agree with the characteristic (i.e., selected 3 or below) they were asked to provide an explanation with comments. Participants who agreed with the statements could also provide comments however were not explicitly asked. In total, over 1,780 comments were reviewed and summarized in this report.

For each characteristic in each product category, a percentage agreement was calculated for both the Minimal and Optimal requirements. The percentage agreement was calculated as the ratio of the sum of number of respondents who selected 4 and 5, to the sum of numbers of respondents who gave any score (from 1 to 5 where 5=fully agree, 4=mostly agree, 3=neither agree nor disagree, 2=mostly disagree and 1=disagree). Consensus for the survey characteristics was pre-specified at greater than 50% of respondents providing a score of at least 4 on the Likert scale.

A classic Delphi process requires at least two rounds of survey ahead of an in-person meeting. Initially, two rounds of the survey were planned, but since 50% consensus for most characteristics was reached after the first round survey, a second round survey was not initiated. Survey results are detailed by characteristic in the individual product category sections.

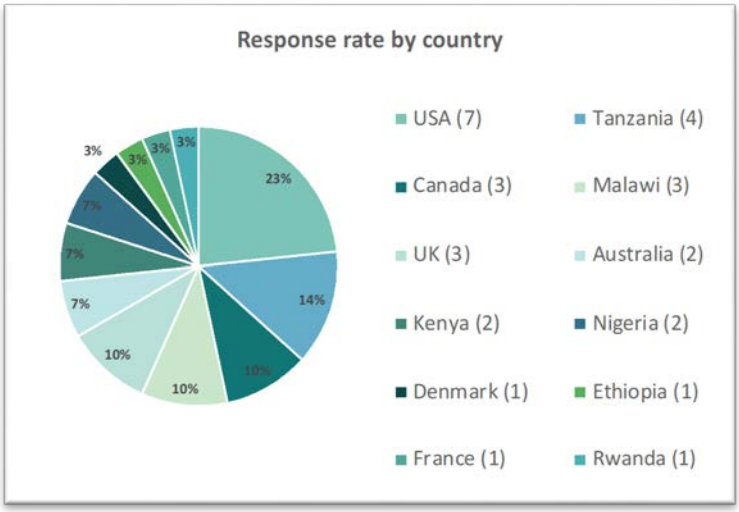
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

**Figure 1: Summary of organizational affiliation for Oxygen Concentrator TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)**




| Respondent type | Percentage |
|---|---|
| Implementer / Clinician (11) | 37% |
| Other (9) | 30% |
| Technical Agency / Researcher (6) | 20% |
| International Body (2) | 7% |
| Advocacy Organization (1) | 3% |
| Ministry of Health (1) | 3% |

**Figure 2: Summary of response rate by country for Oxygen Concentrator TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)**




| Country | Percentage |
|---|---|
| USA (7) | 23% |
| Tanzania (4) | 13% |
| Canada (3) | 10% |
| Malawi (3) | 10% |
| UK (3) | 10% |
| Australia (2) | 7% |
| Kenya (2) | 7% |
| Nigeria (2) | 7% |
| Denmark (1) | 3% |
| Ethiopia (1) | 3% |
| France (1) | 3% |
| Rwanda (1) | 3% |

# Consensus Meeting

On November 20 - 22, 2019 over 69 stakeholders gathered in Stellenbosch, South Africa to focus on building further consensus on areas of discrepancy in opinion within the 16 TPPs. More specifically, characteristics on which fewer than 75% of the respondents agreed, or on which a distinct subgroup disagreed, were discussed. Consensus Meeting moderators presented the results and comments from characteristics with <75% agreement from the Delphi-like survey, the moderators then solicited additional feedback on each characteristic with <75% agreement from the Consensus Meeting participants, and then a proposed change to the TPP characteristic was discussed amongst Consensus Meeting participants. In some cases, Consensus Meeting participants nearly universally agreed on proposed changes. In other cases, Consensus Meeting participants failed to reach 75% consensus on proposed changes. If consensus was not achieved after two votes on proposed changes, meeting participants agreed to move forward and the disagreement is noted in this report.

**Methodology for Mentimeter Voting Results:** Certain proposed changes to TPP characteristics, for which a distinct subgroup disagreed, were anonymously voted on using Mentimeter.com to determine the overall level of agreement and disagreement amongst the Consensus Meeting participants. The Mentimeter Voting Results are presented throughout this report in three distinct categories:

I. Overall vote – Includes all Consensus Meeting participants who voted on Mentimeter.com. To eliminate the possibility of duplicate votes, all respondents were asked to enter their name (to be viewed only by the report authors) and blank (potentially duplicate votes) were eliminated from the overall vote.
II. Clinicians – Includes all Consensus Meeting participants who voted on Mentimeter.com and who designated themselves as a Clinician on Mentimeter.com.
III. Excluding involvement with product development - Includes all Consensus Meeting participants who voted on Mentimeter.com minus those who indicated on a Declaration of Interest form that they are 'currently or have been involved in the development of a candidate technology or product' specific to the Product Category being voted on.

Of the 133 stakeholders that were invited to the meeting, 69 participants were able to attend. Participants comprised country representatives, stakeholders from technical and funding agencies, researchers, implementers and civil society organizations, and representatives from companies working on newborn care technologies (see Appendix B for the Consensus Meeting Participant List). An overview of the discussion for Oxygen Concentrator and final consensus achieved is included in this report. Most characteristics discussed are presented in this report, however, overarching characteristics that applied to all product categories were discussed in unison and are included in the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles. These characteristics are: Target Operator; Target Population; Target Setting; Quality Management; Regulation; User Manual/Instructions; Warranty; Power Source; Battery; Voltage; Power Consumption.

# FINAL TPP – OXYGEN CONCENTRATOR

| Final target product profile for Oxygen Concentrator | | |
|---|---|---|
| **Characteristic** | **Optimal** | **Minimal** |
| ***SCOPE*** | | |
| **Intended Use** | To provide medical oxygen for use in a healthcare setting | |
| **Target Operator** | For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians | |
| **Target Population** | Neonates (born at any gestational age and require ongoing care) | |
| **Target Setting** | Hospitals in low-resource settings, but, may be used in health facilities based on country guidelines | Hospitals in low-resource settings |
| ***SAFETY AND STANDARDS*** | | |
| **Quality Management** [1] | ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes | |
| **Regulation** | At least one of: CE marking, approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g., Japan or Australia or Canada) | |
| ***TECHNICAL CHARACTERISTICS*** | | |
| **Flow Meter** | At least 2 with each 0 to 10 LPM flow meter, min incremental 0.5 LPM | At least 1 [flow meter] with 0 to 10 LPM flow meter, min incremental 0.5 LPM |
| **Minimal Flow Rate** | 0.5 LPM (if used without a flow splitter) | 2 LPM |
| **Flow Rate** | 10 LPM | 8-10 LPM |
| **Time to Reach 95% of Specified Performance** | < 5 Min | |
| **Oxygen Purity** | 93% ± 3% | |
| **Alarms** | Visual and auditory alarms | |
| **Indicators** | Clearly labeled or marked with pictures and language. Audible alerts and diagnostic indicator where possible | UI easy to understand, numbers and displays clearly visible |
| **Mobility** | Whole unit moveable with wheels on at least two feet | |
| **Oxygen Monitor** | Visual and audible status, preferably with color coding for early warning | Visual and audible status |
| **Oxygen Outlet** | Recessed, replaceable metal barbs | |
| **Noise Level** | ≤50 decibels; low as possible | |
| **Weight** | <30 kg | |

| | | |
|---|---|---|
| **Durability and Robustness** | Harsh ambient condition, temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters | Temperature 10-40 °C, humidity 15%-95% elevation up to 2000 meters |
| **Usage Meter** | Non-resettable digital or analog meter displaying cumulative hours of operation | |
| ***PURCHASING CONSIDERATIONS*** | | |
| **Instrument Pricing** | <$500 ex-works | <$1600 ex-works |
| ***UTILITY REQUIREMENTS*** | | |
| **Power Source** | Mains Power | Mains Power |
| **Power Consumption** | <275W at 5 LPM | Scales with delivery output — i.e., consumes less power at lower flow rates |
| **Voltage** | Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz) | |
| ***TRAINING AND MAINTENANCE*** | | |
| **User Instructions** | User manual and additional training materials (checklists, videos, guides) in at least one national official language for the country of intended use. Attached to device with labels and markings where possible | User manual provided in at least one national official language |
| **User Skill Level** | Minimal to none | |
| **Warranty** | 5 years | 1 year |
| **Decontamination** | Reduced recessed areas and need for specialized cleaning procedures or products | Easy to clean flat surfaces, compatible with common disinfecting agents |
| **Preventive Maintenance Interval** | Should not need preventive maintenance more than once a year | Should not need preventive maintenance more than 4 times a year (quarterly) |
| **Technical Skill Maintenance** | Minimally trained technician | Trained technician with training in basic operation and maintenance |
| **Cleaning Interval** | Provide two filters that are durable, washable, easy to remove | Device exterior to be wiped effectively with a mild solution of detergent or cleaning agent (weekly), without connection to mains power. Gross particle filter to be cleaned effectively when removed and washed with soap and water (weekly). Do not clean with alcohol. (User care needed more often in very dusty environments.) [2] |
| **Tools Required** | No specialized tools required | Minimal specialized tools for sieve bed and filter replacement |
| **Filters** | Replaceable washable reusable | |

[1] *There was not 75% voting agreement on the Minimal characteristic. Please refer to the TPP Report discussion for additional detail.*

[2] *Source:* WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 95]

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## Consensus Meeting Summary: Oxygen Concentrator

To arrive at the final TPP for Oxygen Concentrator, we first leveraged the extensive work conducted by PATH in the "Design for reliability: Ideal product requirement specifications for oxygen concentrators for children with hypoxemia in low-resource settings" [3]. We conducted a pre-meeting survey to prioritize the items within this existing TPP to discuss at the Consensus Meeting. Specifically, characteristics that achieved below 75% agreement in the survey results (Table 20). An overview of the discussion at the Consensus Meeting of these characteristics is included below.

- **Flow Meter**
  - For the Optimal characteristic, rather than specifying the flow should be split evenly at 0-5 LPM (Liters Per Minute) in each of the two meters, the range should be 0-10 LPM with the ability to split however the user wants across the two outputs. For the Minimal characteristic, clinicians noted that a flow meter that goes to a minimum of 0.25 increments would be beneficial since 0.5 LPM can even be high for neonates. Product developers noted that from a technical perspective, an easy range is 0-10 with 5% resolution, but that there would be inaccuracy at the lower bound and therefore, would recommend 0-1 graduations. It was noted that a flow splitter paired with an oxygen concentrator would suit requirements at low flow rates and therefore, a flow splitter should always be available with an oxygen concentrator. International agencies noted that: "Ideal setup would be to have a concentrator connected to a 5-way flow splitter, with those flowmeters ranging from 0-2 LPM, with increments of 0.25 LPM or less. In other words, if the optimal requirement of 2 flowmeters is to be able to service two neonatal patients at once, the 0.5 LPM increments on the flowmeters may not be granular enough and so you may need an additional low-flow meter anyway...Optimal [should be] a 10 LPM unit with 2 flowmeters, up to 5 LPM each. Minimal [should be] 8 LPM unit with 1 flowmeter up to 8 LPM."
  - *Minimal: Must have flow splitter with at least 1 with 0 to 10 LPM flow meter, min incremental 0.5 LPM*
    - Overall Vote - 100% Agree (n = 29)
    - Clinicians - 100% Agree (n = 22)
    - Excluding involvement with product development - 100% Agree (n = 29)
- **Flow Rate**
  - No vote required as the rate does not matter when flow splitter is required. The Pre-Meeting Survey report highlighted an emerging theme that there is a lack of clarity on why such high LPM would be used for neonates. One comment noted "I choose higher flow + splitter so that oxygen could be administered to more kids. Ideally you could do this and still titrate at least 1/2-1/4 LPM for individual children". In response, another participant commented "this is a bit of a double-edged sword because you need higher flow rates for CPAP, but low flow (< 1LPM) for standard low-flow O2 therapy. Thus, this would come down to installation, how the concentrators are used in a ward."
  - *Optimal: 10 LPM*
  - *Minimal: 8-10 LPM*
- **Time to Reach 95% of Specified Performance**
  - Consensus achieved in room (without a Mentimeter vote) that Minimal should be the same as Optimal.
  - *Minimal: < 5 Min (same as Optimal)*
- **Alarms**
  - There was a discussion on both the Optimal and Minimal alarms required, and consensus was achieved in the room without a vote. Clinicians noted that visual lights are very helpful. Clinicians requested a sounding alarm if battery or power failure and a visual alarm for flow rate and pressure (i.e., Oxygen

Supply) and ideally for filter status as well. International agencies noted that the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 94] defines alarms as "Audible and/or visual alarms for low oxygen concentration (<82%), low battery and power supply failure. Audible and/or visual alarms for high temperature, low/high/no-flow rate and/or low/high pressure."
    - *Optimal: Visual and auditory alarms*
    - *Minimal: Same as Optimal*
- **Indicators**
    - Consensus was achieved in the room for no change to the Optimal requirement as this was covered in the standards and therefore, there was no need for a separate requirement.
    - *Optimal: Clearly labeled or marked with pictures and language. Audible alerts and diagnostic indicator where possible.*
- **Mobility**
    - A discussion on both the Optimal and Minimal characteristics centered on the mobility requirements for the oxygen concentrator. Clinicians requested two wheels only so that that the equipment cannot be as easily moved. International agencies noted that the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 94] defines the whole unit should be moveable with wheels on at least two legs. Product developers noted that from a technical perspective, brakes can be difficult to implement with small wheels.
    - *Optimal and Minimal: Whole unit should me movable, with wheels on at least two feet*
        - Overall Vote - 100% Agree (n = 24)
        - Clinicians - 100% Agree (n = 19)
        - Excluding involvement with product development - 100% Agree (n = 24)
- **Noise Level (previously titled 'Sound Level – Operating')**
    - Consensus was achieved that the sound level characteristic was referring the operating noise level. Product developers noted that from a technical standpoint, CE mark requires that this be under 50 decibels for operating noise [4]. Consensus was achieved in the room (without a Mentimeter vote) that the "lower the decibel level, the better" and that Optimal and Minimal should be the same. The spirit of the conversation emphasized that the noise levels should be as low as possible to protect the babies hearing.
    - *Optimal: ≤50 decibels; low as possible*
    - *Minimal: Same as Optimal*
- **Cleaning Interval**
    - There was disagreement for the Optimal cleaning interval. Clinicians noted that currently the external filter must be cleaned once a week and the optimal cleaning interval would be once a month. They noted that "none required" for an Optimal cleaning interval was simply not practical. Consensus was achieved in the room (without a Mentimeter vote) that the Minimal requirement should meet the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 95] and the Optimal should meet those guidelines and also be durable, easy to remove, and easy to clean.
    - *Optimal: Provide two filters that are durable, washable, easy to remove*
    - *Minimal: Device exterior to be wiped effectively with a mild solution of detergent or cleaning agent (weekly), without connection to mains power. Gross particle filter to be cleaned effectively when removed and washed with soap and water (weekly). Do not clean with alcohol. (User care needed more often in very dusty environments.)* [2]
- **Preventive Maintenance Interval**
    - There was disagreement for both the Optimal and Minimal preventive maintenance interval characteristics. The discussion highlighted the importance of cost effectiveness and the risk associated with too frequent maintenance intervals given most hospitals have annual preventive maintenance processes. One idea discussed was creating a device that measures oxygen levels and once it drops below a certain level, would flag that maintenance is required. Product developers noted that manufacturers claim 30,000 hours (roughly 3 years) with regular maintenance, but often the true maintenance frequency may vary based on the wide range of operating conditions (i.e., may require more or less maintenance). One suggestion in the Pre-Meeting survey comments was to "measure

oxygen concentration with a calibrated oxygen analyzer" to which another participant clarified that "not all analyzers need to be calibrated (e.g. those with ultrasonic sensors)".

- *Optimal: Should not need preventive maintenance more than once a year*
  - Overall Vote - 83% Agree (n = 23)
  - Clinicians - 79% Agree (n = 14)
  - Excluding involvement with product development - 83% Agree (n = 23)
- *Minimal: Should not need preventive maintenance more than 4 times a year (quarterly)*
  - Overall Vote - 85% Agree (n = 20)
  - Clinicians - 92% Agree (n = 12)
  - Excluding involvement with product development - 85% Agree (n = 20)

- **Replacement Parts and Consumables**
  - Given the discussion on Preventive Maintenance Interval highlighted above, participants noted that this characteristic was too detailed and proposed removing from the final TPP as it would be more applicable to a specification. In light of this, further information on the extensive list of replacement parts recommended in the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 94] is included below:

| ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS | | |
|---|---|---|
| 25 | Accessories (if relevant) | The unit shall include internally and externally mounted filters for cleaning the air intake.<br>All user-removable filters shall be cleanable. Cleaning instructions for filters shall be included in the instructions for use.<br>For two or more simultaneous paediatric patients: 1 x flowmeter stand with minimum range from 0 to 2 L/min.<br>Kink-resistant oxygen tubing with standard connectors (15 m each).<br>2 x adult cannula with 2 m kink-resistant oxygen tubing with standard connectors.<br>4 x infant cannula with 2 m kink-resistant oxygen tubing with standard connectors.<br>4 x neonatal cannula with 2 m kink-resistant oxygen tubing with standard connectors. |
| 26 | Sterilization/ disinfection process for accessories (if relevant) | Disinfection for nasal prongs. |
| 27 | Consumables/ reagents (if relevant) | 5-year supply recommended.<br>1-year supply (adjust quantities per patient load and usage frequency):<br>nasal prongs or nasal catheters (each size for adult, child, infant);<br>child nasal prongs: distal diameter: 1–2 mm;<br>child/infant catheters: 6 or 8 French gauge. |
| 28 | Spare parts (if relevant) | Internal and external filters and spare parts for user fitting (as described in user manual), including:<br>parts supply, including all necessary filters, for 2 years' operation at 15 hours per day.<br>1 x spare battery set for alarm system (if applicable).<br>1 x spare mains power cable, length ≥ 2.5 m.<br>2 x replacement sets of spare fuses (if non-resettable fuses are used).<br>DISS to 6 mm barbed adaptor for each outlet (if relevant).<br>Bidder must give a complete list of the specific spare parts included in their bid.<br>Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan.<br>(Spare parts are not interchangeable between devices of different brands and models, and can vary in their design and lifetime. Medical units to select spare parts ensuring compatibility with the brand and model of the equipment.) |
| 29 | Other components (if relevant) | N/A |

- **User Skill Level**
  - Participants noted that oxygen concentrators were often used by a wide variety of health workers and therefore, the skill level should be "minimal to none" for both the Optimal and Minimal. Consensus was achieved in the room and no vote was taken. Several participants noted that an oxygen concentrator is a medical device whose output is a drug which can be dangerous if not used properly.
  - *Minimal: Minimal to none (same as Optimal)*
- **Power Consumption**
  - There was ample discussion on the power consumption levels. Product developers noted that all commercial machines use a similar amount of power. International agencies commented that there are recommendations in place in the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 94] on appropriate power consumption, which states power efficiency

<70W/L/min. Participants agreed that oxygen concentrators should be as energy efficient as possible and power consumption should be proportionate with use.
    - There was agreement in the room that all characteristics relating to Utility Requirements (e.g., Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting.
    - *Optimal: <275 W at 5 LPM*
    - *Minimal: Scales with delivery output — i.e., consumes less power at lower flow rates*
- **Instrument Pricing**
    - There was disagreement on the Minimal characteristic for instrument pricing. Clinicians stressed the importance of reducing the price to increase access. Participants noted that the average cost of an oxygen concentrator in the market is anywhere from $500 - $1,600 ex-works. Product developers agreed that at a price point of $1,600 ex-works, it would be reasonable from a technical perspective to meet the Minimal characteristics outlined in the TPP.
    - *Minimal: <$1600 ex-works*
- **Voltage**
    - Consensus was achieved in the room that since voltage requirements vary based on local conditions, users need to have the ability to use the machine based on their geographic location. Product developers noted that from a technical standpoint, it is not challenging to manufacture a product for one, or the other, voltage. However, only a stabilizer can allow a machine to do both 50 and 60 Hz.
    - There was agreement in the room that all characteristics relating to Utility Requirements (e.g., Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting.
    - *Optimal and Minimal: Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)*

The following characteristic was not discussed at the TPP Consensus Meeting, however, it was determined that a new characteristic should be added to the TPP with the following justification:

- **Minimal Flow Rate**
    - Some Oxygen Concentrators will not operate below a minimum flow rate. The requirement in the Flow Meter characteristic for flow meter increments of 0.5 LPM only applies above the minimum flow rate of the device. For example, if a device's flow range is 2 LPM – 10 LPM, it is not possible to set the flow to 0.5 LPM, 1 LPM or 1.5 LPM. Rather, it is only possible to set the flow rate from 2 LPM onwards. For neonates, this is relevant if a flow splitter is not being used. If you cannot set to lower flows and there is no flow splitter being used, an Oxygen Concentrator will not prove useful for this neonate population group.
    - *Optimal: 0.5 LPM (if used without a flow splitter)*
    - *Minimal: 2 LPM*

The following characteristics were not discussed at the TPP Consensus Meeting explicitly, however, additional comments were received and incorporated into the discussion:

- **Oxygen Purity**
    - With regard to the Oxygen Purity range, Pre-Meeting survey voting achieved consensus for the Optimal and Minimal characteristic to be (93% ±3%). A theme emerged in the comments though expressing the need to narrow or broaden this range. While pharmacopoeia's guidelines for Oxygen specify 93%, one participant noted that this guideline is "not for individual concentrators". WHO's existing technology specification for concentrators (2015) [5] as well as ISO's 80601-2-69 specified that low oxygen concentration technical alarm condition shall activate before the concentration drops

below 82% volume fraction [7]. International agencies commented that the characteristic should note applicability "at all flow settings" since "Some manufacturers will state different purities for different flow ranges, with lower max purity at the highest flow setting (e.g., 95% at 1 LPM, but 90% at 5 LPM)."
    - *Optimal and Minimal: 93% ±3%*
- **Oxygen Monitor**
    - One theme that arose in the Pre-Meeting survey was confusion on why there were three ranges of oxygen concentration in the Optimal characteristic: "Visual and audible status indicator for three ranges of oxygen concentration preferably with color coding for early warning." One participant clarified that this due to the three ranges indicated in pharmacopoeia: 99, 93 and then 'not for individual concentrators' [8]. International agencies highlighted the importance of clarifying what normal status would be for the audible status indicator.
    - *Optimal: Visual and audible status, preferably with color coding for early warning*
    - *Minimal: Visual and audible status*
- **Durability and Robustness**
    - In the Pre-Meeting survey, we received an additional comment highlighting the importance of considering both heat and humidity simultaneously. Peel's study "Evaluation of oxygen concentrators for use in countries with limited resources" emphasizes the importance of testing manufacturer claims [6]. Additionally, the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [2, p. 95] highlight certain environmental requirements:
        - "Capable of being stored continuously in ambient temperature from 0 °C to 40 °C, RH from 15% to 95% and elevation from 0 to at least 2000 m.
        - Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10 to 40 °C, RH from 15% to 95%, simultaneously, and elevation from 0 to at least 2000 m.
        - For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated."
    - *Optimal: Harsh ambient condition, temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters*
    - *Minimal: Temperature 10-40 °C, humidity 15%-95% elevation up to 2000 meters*
- The following Product Specific ISO Standards were highlighted in the Pre-Meeting survey responses:
    - The product(s) shall conform to the standards stipulated by the International Organisation for Standardisation (ISO) and/or equivalent standards as recognized by any IMDRF member
    - Standards applicable to the product:
        - ISO 80601-2-69:2014 Medical electrical equipment – Part 2–69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.
        - IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
        - IEC 60601-1-2:2014 Medical electrical equipment – Part 1–2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
        - IEC 60601-1-6:2013 Medical electrical equipment – Part 1–6: General requirements for basic safety and essential performance – Collateral standard: Usability.
        - IEC 60601-1-8:2012 Medical electrical equipment – Part 1–8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
        - IEC 60601-1-9:2013 Medical electrical equipment – Part 1–9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design.
        - IEC 60601-1-11:2010 Medical electrical equipment – Part 1–11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health-care environment.
        - ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and EU).

- ISO 14971:2007 Medical devices – Application of risk management to medical devices.
- Compliance with ISO 8359 may be considered.

## Broad Themes and Considerations

At the Consensus Meeting, the following additional themes emerged and are summarized below:

Instrument Pricing
In order to provide a consistent measure of pricing, the ex-works price is included in the TPPs. Participants highlighted that ex-works pricing is not a true measure of landed cost and is often vastly understated to what a procurement agent will pay. One participant from an international NGO noted that there is a "minimum 30% mark-up on the ex-works price." The rationale for using the ex-works price is that it is a reliable measure that can be used for consistent comparison across geographies since distributor markups vary by country and geography.

Utility Requirements
A significant portion of the discussion was devoted to deliberating on how equipment can be designed to work in health facilities with limited electrical infrastructure. Designing the equipment for low-resource conditions often requires back-up batteries which adds to the expense of the technology, as well as the size of the equipment which can pose a challenge in crowded newborn wards. Some participants noted that rather than designing equipment for these facilities with limited electrical infrastructure, to consider whether a broader investment in electrical infrastructure would be a better use of funds. This inherent tradeoff was discussed multiple times when electrical characteristics were discussed.

Additionally, there were a variety of characteristics in the initial survey that related to Utility Requirements (i.e., electricity and power) that varied slightly in title across the TPPs. During the TPP Consensus Meeting, participants agreed that all characteristics relating to Utility Requirements (includes Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting across the product categories. These characteristics have since been reviewed and harmonized into four distinct characteristics (Power Source, Battery, Voltage, and Power Consumption) in the final TPPs.

- **Power Source** - This defines the desired power source for the device and can be broken down into the following categories:
    - *Mains power* - device must be plugged into a mains power source for use
    - *Mains with battery backup* - device must be plugged into a mains power source for use, however, in the case of a power failure, the device has a battery backup that can last a specified period of time
    - *Mains with rechargeable battery* - device has a rechargeable battery that operates both when the device is charged by a mains power source, or, when the device is plugged in (e.g., a mobile phone)
    - *Battery is disposable and replaceable*
    - *No power required (i.e., disposable device)*
- **Battery** - This includes the length of time the rechargeable or disposable battery should function
- **Voltage** - This specifies the preferred voltage conversion if the Power Source utilizes Mains Power. Note that for certain technologies (i.e., Bilirubinometer, Glucometer, Hemoglobinometer, pH monitor, and Pulse Oximeter), the Voltage characteristic is included in reference to the rechargeable battery charger requirements. For example, while the Optimal Voltage characteristic is "None" (i.e., no charging is necessary), the Minimal Voltage characteristic should conform to “the voltage and

frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)" to ensure that the charger for the battery is compliant.

- **Power Consumption** - This specifies the maximum Watts of electricity that the device should consume

Ideally, all devices should be developed to withstand power surges and voltage spikes.

Note that comments received in the Pre-Meeting survey report highlighted the importance of the correct frequency in electrical plugs. It was noted that a universal adaptor would not safely support the conversion of 60Hz equipment to 50Hz and that a machine relying on this method could fail in a short period of time (applicable to Oxygen Concentrator, Warming Crib, Radiant Warmer).

## Delphi-like Survey: Oxygen Concentrator

**Delphi-like survey results for Oxygen Concentrator TPP prior to Consensus Meeting (data as of Oct 25, 2019)**

| | Optimal | | Minimal | | |
|---|---|---|---|---|---|
| **Characteristic** | **Optimal requirement** | **% agreement (n size)** | **Minimal requirement** | **% agreement (n size)** | **Collated comments from Delphi-like survey** |
| **Intended Use** | Optimal: To provide medical oxygen for use in a healthcare setting. | **100% n = 30** | Minimal: Same as Optimal. | **100% n = 30** | 2 comments as summarized below<br>• Consider re-phrasing 'medical oxygen' to 'oxygen for clinical application in a healthcare setting' |
| **Target Operator** | Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians. | **97% n = 31** | Minimal: Same as Optimal | **100% n = 29** | 3 comments as summarized below<br>• Pediatrician / Clinical Officer may decide the settings, but the nurse is the one most likely to use the machine<br>• Separate user for repairing the device / changing the filter |
| **Target Population** | Optimal: Neonates (<28 days) | **65% n = 31** | Minimal: Same as Optimal. | **62% n = 29** | 14 comments as summarized below<br>• Theme: Broaden age range but consider neonates (e.g., flow rates)<br>• Include older infants, children, mothers<br>• Need to consider Flow Meter and Flow Rate characteristics |
| **Target Setting** | Optimal: Hospitals in low-resource settings | **77% n = 31** | Minimal: Same as Optimal. | **77% n = 30** | 10 comments as summarized below<br>• Theme: Broaden vs. Narrow Target Setting<br>o Lower levels of the health system where supply chain does not provide oxygen cylinders and resources adequate<br>o Potentially higher income counties<br>o "On the one hand the mortality tends to be at the village level or first-contact health facility, so we should aim for the smallest health facilities that care for in-patients. On the other hand, the level of skill, training and other resources needed to care for neonates may make it |

| | Optimal | | Minimal | | |
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| | | | | | impractical to go beyond the largest sub-district health centres. Whatever level we choose, it is worthwhile thinking about some technology to help stabilize and transport a neonate who needs referral to a more central level."<br>o Minimal: hospital in resource-limited settings, Optimal: health centres (primary) |
| **International Standard** | Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes. | **75%**<br>**n = 20** | Minimal: Same as Optimal. | **78%**<br>**n = 18** | 10 comments as summarized below<br>• Theme: Add to Additional International Standards vs. Irrelevance<br>• Consider inclusion of ISO 80601-2-69 (current: 2014 though under review) is unique to concentrators, title: Medical electrical equipment -- Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.<br>• Consider adding check additional standards from Family 11 - https://www.iso.org/ics/11/x/<br>• Requirement for CE marking<br>• Alternatively, some respondents commented that having ISO13485 does not necessarily lead to good performance in low-resource settings |
| **Regulation** | Optimal: CE marking or US FDA Clearance | **72%**<br>**n = 25** | Minimal: Same as Optimal. | **70%**<br>**n = 23** | 11 comments as summarized below<br>• Theme: Add more flexibility v. irrelevance of characteristic<br>• Consider additional 'or' options:<br>o Other Stringent Regulatory Authorities – Japan or Australia or Canada<br>o Consider regulatory bodies of Low- and Middle-Income Countries<br>Some respondents did not think that regulatory approval necessarily translated to good performance. |
| **Flow Meter** | Optimal: At least 2 with each 0 to 5 SLPM flow meter, min incremental 0.5 SLPM | **75%**<br>**n = 28** | Minimal: At least 1 with 0 to 8 SLPM flow meter, min incremental 0.5 SLPM | **62%**<br>**n = 26** | 10 comments as summarized below<br>• Change SLPM to LPM<br>• Theme: Merge Flow Meter and Flow Rate characteristics for clarity<br>• Theme: Higher Flow (10 lpm) Oxygen Concentrators have advantages but may create confusion as well between flow meter and flow splitter<br>o Could be used as a back up flow generator for bCPAP during power outages<br>o If you have a splitter, could get oxygen to more babies<br>• Theme: Need smaller increments<br>o Neonates who are on long term oxygen need minimum titration capability of 1/4 liter (especially neonates with sufficient prematurity to cause chronic lung disease ... the |

| | Optimal | | Minimal | | |
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| | | | | | ability to do small titrations to get them off oxygen prior to day of life 30 is important)<br>o "In level 2 nurseries we have a few modified flow meters that will let you titrate at as little as 1/8 of a liter in order to help us wean kids off oxygen"<br>• Theme: Other Suggested Alternatives<br>o "Should be at least 2 flow meters for efficiency"<br>o "I don't think we should encourage the inefficient way concentrators are typically used - moved around the ward and used for one or two children at a time"<br>o "Low-pressure piping system to distribute oxygen from a unified concentrator/low-pressure store/backup cylinder system (automatically choosing the cheapest source available at the time). So we don't really care what the concentrator's flow meter is like, and we see no value in having two flow meters. It is not widely known that a typical concentrator uses the same amount of electricity whether it is running at 0.5 LPM or 10 LPM. There is no efficiency gain in running below full capacity, so we prefer to (i) store 'excess' oxygen for use when the concentrator is off, and (ii) automatically switch the concentrator off when the store is full, to minimize electricity use." |
| **Flow Rate** | Optimal: 10 SLPM | **69%**<br>**n = 29** | Minimal: 8-10 SLPM | **50%**<br>**n = 28** | 15 comments as summarized below<br>• Theme: Lack of clarity on why such high LPM for neonates (likely due to separation of Flow Meter and/or Splitter)<br>o I choose higher flow + splitter so that oxygen could be administered to more kids. Ideally you could do this and still titrate at least 1/2-1/4 LPM for individual children<br>o 5 LPM (most popular mention)<br>o "No neonate requires 10 LPM"<br>o Minimal should be 8 LPM<br>o 2 LPM would be helpful<br>o Minimal flow rate can be less than 8 SLPM especially for neonates |
| **Time to Reach 95% of Specified Performance** *(corrected from 'Pressure')* | Optimal: < 5 Min | **85%**<br>**n = 27** | Minimal: <30 Min | **46%**<br>**n = 26** | 15 comments as summarized below<br>• Theme: 30 minutes is too long<br>o 5 minutes already met with most commercially available devices<br>o 10 minutes<br>o 3 minutes |

| | Optimal | | Minimal | | |
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| **Oxygen Purity** | Optimal: 93% +- 3% | **80%**<br>**n = 30** | Minimal: Same as Optimal. | **75%**<br>**n = 28** | 10 comments as summarized below<br>• Theme: Respondents expressed need to narrow or broaden this range<br>o This aligns with a few pharmacopoeia's guidelines for Oxygen 93<br>o WHO's existing tech specs for concentrators (2015) as well as ISO's 80601-2-69 have indicated greater than or equal to 82% (so alarms set etc.)<br>o FiO2 achieved from 95% would be +/- 45.5%, and FiO2 achieved from 82% would be +/-41%<br>o According to ECRI, most can meet 90% at all flow settings.<br>o For minimal, this could be relaxed to 90% +/- 3<br>o This may be too strict for actual testing. As reported by manufacturer's this is fine, but the level varies depending on the flow rates and other external environmental factors |
| **Alarms** | Optimal: Audible and/or visual alarms for high temperature, flow rate and pressure | **74%**<br>**n = 31** | Minimal: Same as Optimal. | **67%**<br>**n = 30** | 12 comments as summarized below<br>• Theme: A range of alarms were mentioned<br>o Low battery or power failure (alarm if power failure) - needs immediate response by healthcare worker<br>o Oxygen purity (alarm if <85% or < 82%) - needs rapid response by healthcare worker<br>o High or low pressure/flow/temperature (where response is to call a technician)<br>• Note: Some machines use an internal 9V battery for the alarms. If it is not replaced (as is common) then the alarms do not work |
| **Indicators** | Optimal: Clearly labeled or marked with pictures and language. Audible alerts and diagnostic indicator where possible | **73%**<br>**n = 30** | Minimal: UI easy to understand, numbers and displays clearly visible | **86%**<br>**n = 28** | 8 comments as summarized below<br>• Theme: Provide additional clarity on what is meant by diagnostic indicator<br>o Diagnostic indicators + informing necessary action(s) are desirable<br>o Change diagnostic indicator to low oxygen indicator<br>o Electrical power input requirements (voltage, frequency, socket type) |
| **Mobility** | Optimal: Four antistatic swivel castors, two with brakers, integrated handle | **70%**<br>**n = 27** | Minimal: Four wheels | **73%**<br>**n = 26** | 10 comments as summarize below<br>• Theme: Variation in perceived advantages of wheels and breaks<br>o UNICEF-WHO spec: Whole unit to be movable with wheels on at least two feet<br>o Not worth it if increases cost<br>o Always swivel wheels |

| | Optimal | | Minimal | | |
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| | | | | | o "Is there space for breaks? Wheels are so small!"<br>o We discourage the moving of concentrators around the ward. In some of our installations we have had to remove or immobilise the wheels<br>o Important to be easily mobile to accommodate range of clinical situations and to move around neonatal units<br>o No concentrators have brakes on them - it is another potential failure point on the device. Suggest making minimal and Optimal the same at "four wheels" |
| **Oxygen Monitor** | Optimal: Visual and audible status indicator for three ranges of oxygen concentration preferably with color coding for early warning. | **82%**<br>**n = 28** | Minimal: Visual and audible status. | **89%**<br>**n = 28** | 9 comments as summarized below<br>• Theme: Confusion as to why three ranges of oxygen vs. two<br>o Oxygen purity <85%<br>o Oxygen purity above or below 90% |
| **Oxygen Outlet** | Optimal: Recessed, replaceable metal barbs | **85%**<br>**n = 26** | Minimal: Recessed, replaceable metal or plastic barbs | **84%**<br>**n = 25** | 7 comments as summarized below<br>• Nothing currently meets Optimal<br>• Plastic is easily damaged |
| **Sound Level** | Optimal: ≤50 decibels | **84%**<br>**n = 25** | Minimal: 50 decibels | **65%**<br>**n = 23** | 12 comments as summarized below<br>• Theme: <50 dB easily obtainable by current machines vs. nothing currently meets 50 dB<br>• EC 60601-1-8 has, in the latest amendment 1 issued in 2012, a number of measurements are required according to Annex F in ISO 3744, with the measurements averaged |
| **Decontamination** | Optimal: Reduced recessed areas and need for specialized cleaning procedures or products | **80%**<br>**n = 30** | Minimal: Easy to clean flat surfaces, compatible with common disinfecting agents | **97%**<br>**n = 29** | 9 comments as summarized below<br>• Theme: Access to filter and or humidity / water container<br>• Theme: Optimal and Minimal should be switched |
| **Weight** | Optimal: <30 kg | **79%**<br>**n = 29** | Minimal: Same as Optimal. | **81%**<br>**n = 27** | 8 comments as summarized below<br>• Theme: Variability in perceived advantages of weight<br>o Seldom needs to be moved<br>o WHO-UNICEF interagency spec is less than 27kg so Optimal could be less<br>o Weight is not important except for freight costs<br>o Ideally less than 20 kg or 23 kg could be carried by staff |

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| **User Instructions** | Optimal: User manual and additional training materials (checklists, videos, guides) in English and local language. Attached to device with labels and markings where possible. | **72%**<br>**n = 29** | Minimal: Instruction manual provided. | **68%**<br>**n = 28** | 11 comments as summarized below<br>• A variety of hard and soft copy materials mentioned with particular mentions of difficulty in reading a user manual and preference for videos so people can see vs. read<br>• All claims must be filed with the regulatory dossier, so this is not as straight forward as a simple translation. Appropriate, professional translations are a must and are costly to the manufacturer. Additionally, local language varies greatly across a country and is often-times not even the official language of the country and so this may not be a reasonable ask of manufacturers.<br>• English, French and Portuguese most critical languages |
| **Durability and Robustness** | Optimal: Harsh ambient condition, temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters | **88%**<br>**n = 26** | Minimal: temperature 10-40 °C, humidity 15%-95% elevation up to 2000 meters | **88%**<br>**n = 25** | 14 comments as summarized below<br>• Theme: Additional Durability and Robustness considerations mentioned<br>o Dust<br>o Dirty electricity<br>o As demonstrated by Peel, important to test manufacturer claims: https://onlinelibrary.wiley.com/doi/full/10.1111/anae.12260<br>• Theme: May be too aggressive and would require existing manufacturers to resubmit for regulatory which is not likely<br>• WHO-UNICEF spec:<br>o Capable of being stored continuously in ambient temperature from 0°C to 40°C, RH from 15% to 95% and elevation from 0 to at least 2000 m<br>o Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10 to 40 °C, RH from 15% to 95%, simultaneously, and elevation from 0 to at least 2000 m<br>o For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated |
| **Usage Meter** | Optimal: Non-resettable digital or analog meter displaying cumulative hours of operation. | **85%**<br>**n = 26** | Minimal: Same as Optimal. | **80%**<br>**n = 25** | 4 comments as summarized below<br>• Could be useful to re-set the timer after changing the sieve bed and other spare part |
| **Cleaning Interval** | Optimal: None Required. | **66%**<br>**n = 29** | Minimal: Weekly cleaning of external course filter. | **75%**<br>**n = 28** | 16 comments as summarized below<br>• Theme: Optimal and minimal are not realistic<br>• Optimal cleaning interval is required as dust can accumulate |

| | Optimal | | Minimal | | |
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| | | | | | • None required is not realistic. The concentrators that have claimed that previously have failed to deliver. I worry this will provide false reassurance. I suggest keeping Optimal same as minimal<br>• Optimal: not more than weekly cleaning of easily accessible external filter<br>• Minimal: not more than monthly cleaning of other filters/components<br>• WHO-UNICEF<br>o Device exterior to be wiped effectively with a mild solution of detergent or cleaning agent (weekly), without connection to mains power<br>o Gross particle filter to be cleaned effectively when removed and washed with soap and water (weekly)<br>o Do not clean with alcohol<br>o (User care needed more often in very dusty environments) |
| **Preventive Maintenance Interval** | Optimal: Minimal to none | **64%**<br>**n = 28** | Minimal: Every 24 months | **68%**<br>**n = 25** | 14 comments as summarized below<br>• Theme: Optimal and minimal are not realistic<br>• Suggested Ranges<br>o 3 months<br>o 6 months<br>o 12 months<br>o Regular<br>o As per manufacturer recommendation<br>o 24 month interval is not often enough to be realistic for any current products<br>o Minimal to none is not realistic<br>• Provide suggestions for preventative maintenance<br>o Test power failure alarms<br>o Measure operating pressure with pressure test gauge<br>o Measure oxygen concentration with a calibrated oxygen analyzer<br>o Repair internal components as needed<br>o Maintain spare-parts inventory |
| **Replacement Parts and Consumables** | Optimal: None required | **60%**<br>**n = 25** | Minimal: None required for 24 months | **71%**<br>**n = 24** | 16 comments as described below<br>• Theme: Optimal and minimal are not realistic<br>• Suggested Ranges and Parts<br>o Not possible to have no parts and consumables replacement needed<br>o As per manufacturer recommendation<br>o Every 3 months<br>o 6-12 monthly replacement of filters, and >24 monthly other spare parts<br>o Fuses<br>o Recommend five years of filters and spare parts be organized at the time of purchase and replaced when used |

| | Optimal | | Minimal | | |
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| | | | | | ▪ Internal and external filters and spare parts for user fitting (as described in user manual), including:<br>• Parts supply, including all necessary filters, for 2 years operation at 15 hours per day.<br>• 1 x spare battery set for alarm system (if applicable).<br>• 1 x spare mains power cable, length 2.5 m.<br>• 2 x replacement sets of spare fuses (if non-resettable fuses are used)<br>• DISS to 6mm barbed adaptor for each outlet (if relevant)<br>o Bidder must give a complete list of the specific spare parts included in their bid<br>o Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan<br>o (Spare parts are not interchangeable between devices of different brands and models, and can vary in their design and lifetime. Medical units to select spare parts ensuring compatibility with the brand and model of the equipment.) |
| **Warranty** | Optimal: 5 years | **85%**<br>**n = 27** | Minimal: 1 year | **65%**<br>**n = 26** | 11 comments as summarized below<br>• Theme 1 year too short \| 5 years too long<br>• Suggested Ranges:<br>o 2 years<br>o "To honor a 5 year warranty, you will have to have strong in-country representation. An extended warranty is a degree of assurance of the above, and this will come at a cost. Manufactures of concentrators willing to extend a warranty from 2-5 do so at a cost. What might be more useful is that during any procurement, consideration be given to establishing a SLA with an in-country rep. In this case, you can take care of any major PPM requirements, as well as "swap out" |

| | Optimal | | Minimal | | |
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| | | | | | in the event of a break-down, and there is no discussion of warranties and no need for spares and an in-country source for consumables." |
| **Technical Skill Maintenance** | Optimal: Minimally trained technician | **76%**<br>**n = 29** | Minimal: Trained technician with training in basic operation and maintenance | **89%**<br>**n = 27** | 6 comments as summarized below<br>• Lack of clarity on what minimally trained technician means<br>• How do we quantify or measure this? |
| **Tools Required** | Optimal: No specialized tools required | **79%**<br>**n = 28** | Minimal: Minimal specialized tools for sieve bed and filter replacement | **81%**<br>**n = 27** | 7 comments as summarized below<br>• Minimal should still be 'no specialized tools'<br>• Filter replacement should require 'no specialized tools'<br>• Will always require specialized tools, otherwise, anyone can open and tamper<br>• Manufacturer to specify which tools are required to perform maintenance tasks:<br>o Test power failure alarms<br>o Measure operating pressure with pressure test gauge<br>o Measure oxygen concentration with a calibrated oxygen analyzer<br>o Repair internal components as needed<br>o Maintain spare-parts inventory |
| **User Skill Level** | Optimal: Minimal to none. | **68%**<br>**n = 28** | Minimal: Same as Optimal. | **67%**<br>**n = 27** | 8 comments as summarized below<br>• Lack of clarity on what minimal means<br>• None does not make sense |
| **Electrical Plug** | Optimal: Universal conversion power adapter, compatible with local power outlet, rated above amperage voltage requirements | **79%**<br>**n = 28** | Minimal: Compatible with local power outlet, rated above amperage voltage requirements | **93%**<br>**n = 27** | 8 comments as summarized below<br>• Theme: Additional suggestions provided<br>o "Universal" adaptor will not convert 60Hz equipment to 50Hz. Machine will fail within 3 months<br>o This is always a very solvable issue. It's the actual voltage and FREQUENCY of device that's most important, as well as voltage stabilizers and surge suppressors<br>o Locally compatible plug preferred over conversion adapter to avoid misuse<br>o Need surge (up to 330 V) and dip protection |
| **Filters** | Optimal: Replaceable washable reusable | **86%**<br>**n = 29** | Minimal: Same as Optimal | **86%**<br>**n = 28** | 5 comments as summarized below<br>• Theme: Additional suggestions provided:<br>o This is adequate for the external filter. But usually there is a fine particle filter internally that is typically made of felt and needs replacement, especially after the dusty season<br>o Which filters?<br>▪ Bacteria filter definitely cannot be washed and |

| | Optimal | | Minimal | | |
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| | | | | | should not really need replacing<br>▪ Gross particle definitely washable & reusable<br>▪ Air intake (compressor) filter is HEPA and washing them is not a possibility as it damages the weave or fibres that make it effective in the first place<br>o Incompatible with Cleaning Interval |
| **Power Consumption** | Optimal: 275 W at 5 SPLM | **68%**<br>**n = 19** | Minimal: Scales with delivery output — i.e., consumes less power at lower flow rates. | **65%**<br>**n = 20** | 10 comments as summarized below<br>• Theme: Optimal and minimal are not realistic<br>• Nothing currently meets these requirements<br>• 5 LPM inconsistent with 8-10 LPM mentioned above |
| **Surge Protection** | Optimal: Integrated | **93%**<br>**n = 29** | Minimal: External | **79%**<br>**n = 28** | 12 comments as summarized below<br>• Theme: Internal Surge Protection is not necessarily ideal<br>o Quality of surge protector depends on how terrible the power is<br>o For many African contexts, an adequate surge protector will weigh as much as the concentrator itself and be quite bulky and cost <200USD<br>o I worry this might encourage manufacturers to put in low quality surge protectors that won't actually do the job<br>o More costly?<br>• Theme: External Surge Protection is not necessarily ideal either<br>o External can be damaged, stolen, misapplied for other equipment<br>o More costly?<br>• Theme: Surge protection not as important as voltage<br>o In our experience surge protection is less important than lifting low voltages towards the optimum. |
| **Voltage** | Optimal: 110-240 50-60hz | **83%**<br>**n = 23** | Minimal: 220-240 50-60hz | **71%**<br>**n = 21** | 8 comments as summarized below<br>• As per local requirements |
| **Instrument Pricing** | Optimal: <$500 ex-works | **83%**<br>**n = 24** | Minimal: <$1600 ex-works | **61%**<br>**n = 23** | 9 comments as summarized below<br>• Theme: Minimal seems high for an Oxygen Concentrator unless you have a flow splitter; $1,000<br>• Theme: Don't buy cheap; if you do, check manufacturers claims independently |

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# APPENDICES

## Appendix A: Delphi-like Survey Respondent Organizational Designation

3rd Stone Design
Abuja University Teaching Hospital
Alex Ekwueme Federal University Teaching Hospital Abakaliki
Baylor College of Medicine
BC Children's Hospital
Burnet Institute
CCBRT Dar es Salaam
CENETEC-Salud
Center for Public Health and Development (CPHD)
Children's Hospital of Philadelphia
Christian Medical College, Vellore
Clinton Health Access Initiative
College of Medicine, University of Lagos
College of Medicine, University of Malawi
Dartmouth
Day One Health
Diamedica UK Ltd
D-Rev
Egerton University - Nakuru County Referral Hospital
ETH Zurich
Fishtail Consulting
FREO2 Foundation Australia
Global Strategies
Hawassa University
Independent Biomedical Engineer
Institute for Healthcare Improvement
intelms.com
Kamuzu Central Hospital
Kamuzu College of Nursing
Kemri-Wellcome Trust
Kenya Paediatric Association
Komfo Anokye Teaching Hospital
Malawi-Liverpool Wellcome Trust
Mama Lucy Hospital
Masimo
Mbarara University of Science and Technology
McGill University Health Centre
McMaster University
Medecins Sans Frontieres
Mediquip Global Limited
Ministry of Health, Senegal
mOm Incubators
MRC Gambia at LSHTM
Muhimbili National Hospital
Muhimbili University of Health and Allied Sciences (MUHAS)
Neopenda
No designation listed (10)
Pediatric and Child Health Association in Malawi

Pumwani Hospital
Queen Elizabeth Central Hospital
Rice 360 Institute for Global Health
Royal Children's Hospital and Centre for International Child Health (University of Melbourne)
Save The Children
Texas Children's Hospital
The University of Queensland
UCSF and London School of Hygiene & Tropical Medicine
UNICEF
University of Alabama at Birmingham
University of British Columbia
University of Global Health Equity
University of Maiduguri Teaching Hospital, Maiduguri
University of Nairobi
UNTH, Enugu

## Appendix B: Consensus Meeting Participation

Albert Manasyan (University of Alabama Birmingham)
Anna Worm
Antke Zuechner (CCBRT)
Audrey Chepkemoi (Moi Teaching and Referral Hospital)
Bentry Tembo (Kamuzu Central Hospital)
Bev Bradley (UNICEF)
Casey Trubo (D-Rev)
Chishamiso Mudenyanga (Clinton Health Access Initiative)
Danica Kumara (3rd Stone Design)
Daniel Wald (D-Rev)
Edith Gicheha (Kenya Pediatric Research Consortium)
Emily Ciccone (University of North Carolina - Chapel Hill)
Emmie Mbale (PACHA)
Grace Irimu (University of Nairobi)
Guy Dumont (The University of British Columbia)
Helga Naburi (Muhimbili National Hospital)
Jeffrey Pernica (McMaster University)
John Appiah (Kumfo Anokye Teaching Hospital)
Jonathan Strysko (Children's Hospital of Philidelphia/Princess Marina Hospital)
Joy Lawn (London School of Hygiene and Tropical Medicine)
Lincetto Ornella (WHO)
Liz Molyneux (College of Medicine, Malawi)
Lizel Lloyd (Stellenbosch University)
Mamiki Chise
Marc Myszkowski
Maria Oden (Rice University)
Martha Franklin Mkony (Muhimbili National Hospital)
Martha Gartley (Clinton Health Access Initiative)
Mary Waiyego (Pumwani Maternity Hospital)
Matthew Khoory (mOm Incubators)
Melissa Medvedev (University of California, San Francisco; London School of Hygiene and Tropical Medicine)
Msandeni Chiume (Kamuzu Central Hospital)
Naomi Spotswood (Burnet Institute)
Norman Lufesi (Ministry of Health Malawi)
Pascal Lavoie (University of British Columbia)
Queen Dube (College of Medicine, Malawi)
Rachel Mbuthia (GE Healthcare)
Rebecca Richards-Kortum (Rice University)
Rhoda Chifisi (Kamuzu Central Hospital)
Rita Owino (GE Healthcare)
Robert Moshiro (Muhimbili National Hospital)
Ronald Mbwasi (Kilimanjaro Christian Medical Centre)
Sam Akech (KEMRI-Wellcome Trust Research Programme)
Sara Liaghati-Mobarhan (Rice University)
Sona Shah (Neopenda)
Steffen Reschwamm (MTTS)

Steve Adudans (CPHD/MQG)
Thabiso Mogotsi (University of Botswana)
Walter Karlen (ETH Zurich)
Zelalem Demeke (Clinton Health Access Initiative)

## Appendix C: Abbreviations

| | |
|---|---|
| °C | Degrees Celsius |
| bCPAP | Bubble continuous positive airway pressure |
| bpm | Beats per minute / Breaths per minute |
| CE Mark | Conformité Européenne – certification mark |
| cm | Centimeters |
| $cm^2$ | Centimeter squared |
| CRP | C-reactive protein |
| CPAP | Continuous positive airway pressure |
| DHS | Demographic and health survey |
| FDA | Food and Drug Administration |
| HIS | Health information system |
| Hz | Hertz |
| IMR | Infant mortality rate |
| ISO | International Standards Organization |
| IV | Intravenous |
| KMC | Kangaroo Mother Care |
| kg | Kilogram |
| LPM | Liters per minute |
| LRS | Low-resource settings |
| MCH | Maternal and child health |
| MDG | Millennium Development Goal |
| Mg/dL | Milligrams per deciliter |
| mL/hr | Milliliters per hour |
| mmol/L | Millimoles per liter |
| µmol/L | Micromoles per liter |
| MMR | Maternal mortality rate |
| MNCH | Maternal, newborn, and child health |
| MNH | Maternal and neonatal health |
| nm | Nanometer |
| NMR | Neonatal mortality rate |
| PCT | Procalcitonin |
| PEEP | Positive end-expiratory pressure |
| PR | Pulse rate |
| RDS | Respiratory distress syndrome |
| ROP | Retinopathy of prematurity |
| SpO2 | Peripheral saturation of oxygen |
| SDG | Sustainable Development Goal |
| TFR | Total fertility rate |
| U5MR | Under-5 mortality rate |
| UNFPA | United Nations Population Fund |
| USAID | U.S. Agency for International Development |
| uW | Micro Watts |
| W | Watt |
| WHO | World Health Organization |